REMARKS

A detailed listing of all claims that are under examination in the application is presented above, with an appropriate defined status identifier. No amendments to the claims have been made with the present Amendment. The listing of the pending claims above is provided solely for the convenience of the Examiner.

Claims 16-18, 20, 22, 25, and 27-30 are pending in the application, with claim 16 being the independent claim. Claims 1-15, 19, 21, 23, 24, and 26 were cancelled by previous amendment.

A Sequence Listing is submitted herewith, and the specification has been amended to insert sequence identification numbers (SEQ ID NOs) at appropriate places within the text for each disclosed amino acid sequence, in response to the Notice issued by the Office requiring Applicants to comply with the requirements set forth in 35 U.S.C. §§ 1.821-1.825.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. The Double Patenting Rejection

The Examiner provisionally rejects claims 16-18, 20, 22, 25, and 27-30 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 7, 19, 20, 23, and 27 of co-pending Application No. 10/498,215. (Office Action, at page 3, lines 4-11.)

Applicants respectfully assert that the present claims would not have been obvious in view of 7, 19, 20, 23, and 27 of co-pending Application No. 10/498,215 ("the '215 application"). The present claims are directed to a sustained release preparation comprising a combination of two types of microcapsules: (1) a long-term releasing microcapsule, which gradually releases a GnRH agonist for 5 months or longer, and (2) a short-term releasing microcapsule, which gradually releases a GnRH agonist for shorter than 5 months so that the blood concentration of the GnRH agonist within one week after administration is about 2 ng/mL or higher.

In contrast, the claims of the '215 application – and the application disclosure itself - are directed to a process for producing a sustained release composition for releasing the active

component for a long period of time. There is no teaching or suggestion in the '215 application regarding combination of a long-term releasing microcapsule and a short-term microcapsule to produce a preparation exhibiting stable sustained release of an active agent.

Present claims 16-18, 20, 22, 25, and 27-30 would therefore not be obvious in light of the pending claims of the '215 application.

Applicants submit that the obviousness-type double patenting rejection of claims 16-18, 20, 22, 25, and 27-30 under 35 U.S.C. § 103(a) has been overcome and respectfully request that the Examiner withdraw the rejection.

II. The Rejection of the Claims Under 35 U.S.C. § 103

The Examiner maintains the rejections of claims 16-18, 20, 22, 25, and 27-30 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Okada *et al.*, U.S. Pat. No. 6,113,943 ("Okada") in view of Hutchinson, U.S. Pat. No. 5,889,110 ("Hutchinson"). Applicants respectfully traverse this rejection.

Specifically, the Examiner continues to believe that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention, because "Okada teaches a sustained release preparation comprising a polymer of lactic acid having an average molecular weight of about 25,000 to about 60,000 and a physiologically active peptide, wherein the peptide is leuprorelin . . . and which releases the physiologically active substance over a period of at least five months . . .", and Hutchinson "teaches extended release pharmaceutical compositions, [with] suitable pharmacologically active peptides such as LHRH, leuprorelin," "discloses experiments for the release of goserelin over relatively short periods of time of 5-7 weeks" and "teaches a lactide/glycolide co-polymer having a weight average molecular weight of about 15,000 Da . . . ." (Office Action, at page 4, lines 4-22, and page 5, lines 7-11.)

Applicants maintain that one of ordinary skill in the art, in view of Okada and Hutchinson, would not have arrived at the sustained release preparation as presently claimed, for the reasons discussed in their responses to previous Office Actions, including Applicants' responses filed on October 17, 2008, April 14, 2008, and October 31, 2007, which are incorporated into the present Amendment and Reply.

For example, as explained in Applicants' October 17, 2008 response, Okada teaches sustained release preparations containing lactic acid polymers having a weight average molecular weight higher than that of the lactic acid polymers in Applicants' claimed sustained release preparation. Hutchinson, moreover, appears to suggest that the drug release period of a sustained release preparation can be controlled by changing the weight average molecular weight of the polyester (e.g., lactic acid polymer) in the sustained release preparation, which can be viewed as teaching *away* from the idea of producing sustained release preparations by combining *two* kinds of microcapsules, each containing polymers having the recited molecular weight ranges. Applicants also note again that even if Okada and Hutchinson were combined, they still would not teach or suggest the advantages of the present invention as disclosed in the present specification.

Thus, for at least these reasons, neither Okada nor Hutchinson teach or suggest combining a long-term releasing microcapsule and a short-term releasing microcapsule to produce a preparation exhibiting stable sustained release of a GnRH agonist over a long period of time. Applicants respectfully submit that the Examiner is applying hindsight in arriving at his conclusion that Applicants' claimed sustained-release preparation would have obvious in light of theses two references.

Applicants further note that Okada may disclose a sustained–release preparation showing sustained release over a period of at least about 5 months, but Okada fails to teach or suggest any *combination* of a long-term releasing microcapsule and a short-term releasing microcapsule so as to produce a preparation exhibiting stable sustained release of a GnRH agonist over a long period of time, as presently claimed. In fact, Applicants cannot find any prior art suggesting a combination of a long-term releasing microcapsule and a short-term microcapsule to produce a preparation exhibiting stable sustained release of GnRH agonist over a long term of at least 5 months as well as having an increased amount of agonist release at an early stage of administration.

Accordingly, a person of ordinary skill in the art, at the time the invention was made, would not have arrived at the claimed sustained release preparation in view of the disclosures in Okada and Hutchinson. Thus, the sustained release preparations currently claimed would not have been *prima facie* obvious to one of ordinary skill in the art.

Applicants submit that the rejection of claims 16-18, 20, 22, 25, and 27-30 under 35 U.S.C. § 103(a) has been overcome and respectfully request that the Examiner withdraw the rejection.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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